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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,657	01/24/2001	Francisco Cabrera	Mo-6151/MD-96-6	3791

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EXAMINER

SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 10/02/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/768,657

Applicant(s)

CABRERA, FRANCISCO

Examiner

Humera N Sheikh

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the Amendment and the request for an extension of time (1 month), both filed 06/26/02.

Claims 1-8 are pending. Claims 1-8 remain rejected.

The 35 USC 112, second paragraph rejections have been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lange *et al.* (US Pat. No. 5,152,986) or Vetter *et al.* (US Pat. No. 5, 808,076), (collectively, "Lange" and "Vetter").

Lange *et al.* disclose a solid orally administered medicament preparation comprising quinolonecarboxylic acid derivatives, polyethylene glycols and polyvinyl alcohols used in feedstuffs for animals for the improvement of masking flavor and intake

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of the composition (see reference column 1, lines 1-11); (column 2, lines 48-66); (column 3, lines 36-47); (column 5, lines 10-32); (column 6, lines 19-26, 52-66); (column 11, lines 21-52); (column 12, lines 1-31).

Claims 1-2 and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Vetter et al.

Vetter et al. disclose a solid oral preparation comprising quinolone- or naphthyridonecarboxylic acids, polyethylene glycols and polyvinyl alcohols for use in feed formulations, which mask bitter flavoring and fight bacterial infections in humans and animals (see reference column 1, lines 1-45); (column 2, lines 44-58); (column 3, lines 50-67); (column 4, lines 1-27); (column 5, lines 19-35); (column 8, lines 10-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lange et al. (US Pat. No. 5,152,986) or Vetter et al. (US Pat. No. 5,808,876) in view of Pollinger et al. (US Pat. No. 5,695,784, collectively, "Pollinger").

As pointed out above, Lange disclose a solid oral preparation comprising quinolonecarboxylic acid, polyethylene glycols and polyvinyl alcohol wherein the preparation is admixed into animal feed to mask the bitter taste and therefore, improve the animal's intake and consumption of the feed formulation (see reference column 1, lines 1-11); (column 2, lines 48-66); (column 3, lines 36-47); (column 5, lines 10-32); (column 6, lines 19-26, 52-66); (column 11, lines 21-52); (column 12, lines 1-31).

As pointed out above, Vetter disclose a solid, homogeneously dispersed oral preparation comprising quinolone- or naphthyridonecarboxylic acids, polyethylene glycols and polyvinyl alcohols for use with taste-sensitive animals for the treatment of bacterial infections (see reference column 1, lines 1-45); (column 2, lines 44-58); (column 3, lines 50-67); (column 4, lines 1-27); (column 5, lines 19-35); (column 8, lines 10-45).

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Lange or Vetter, while teaching preparations comprising quinolone- or naphthyridonecarboxylic acids in animal feeds for masking bitter tastes, are lacking in the teachings of shellac in the quinolonecarboxylic acid formulation. It is well within the skill of the pharmaceutical art that various binders and film-forming agents can be implemented, in combination, to increase the mechanical stability and strength of oral preparations. Such skill is also evident from the reference of Pollinger et al. (US Pat. No. 5,695,784).

Pollinger teach flavor-masked pharmaceutical compositions comprising naphthyridone- and quinolone-carboxylic acid, polyethylene glycol, polyvinyl alcohol and shellac (see reference column 1, lines 30-67); (column 4, lines 9-59); (column 5, lines 7-15, 45-53). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use shellac in combination with quinolone- or naphthyridonecarboxylic acids to mask ill-flavored compositions in feed or foodstuff applications, with the expected result of obtaining an edible, improved tasting, therapeutic composition for the treatment of bacterial infections in humans and animals.

Lange or Vetter do not teach the exact claimed ratios. However, in the absence of showing the criticality, it is deemed obvious to manipulate the ranges to obtain the best possible results.

Respons to Argum nts

Applicant's arguments filed 06/26/02 have been fully considered but they are not persuasive.

The applicant argued in regard to the 35 USC 102(b) rejections of Lange or Vetter in that, "Lange et al. and Vetter et al. do not disclose solid phase dispersion and the issue is whether they teach elements of the claim in the same arrangement as the claims".

The examiner respectfully disagrees and it is the examiner's position that the prior art of *Lange* contributes a matrix because drug is suspended within resins and thickeners – note column 3, lines 36-38 where resins actively bind the active ingredient. Also note col. 6, lines 18-26, where polymeric thickeners are employed to increase the viscosity of the solid dispersion.

Regarding *Vetter*, Vetter specifically teaches at col. 2, lines 51-58, polymeric carriers that would constitute a matrix of a solid dispersion having an active ingredient dispersed therein.

The applicant argued in regard to the 35 USC 103(a) rejection of Lange or Vetter, in view of Pollinger *et al.*, that there is a failure of the references to teach a solid phase dispersion comprising the active ingredient and an insoluble matrix.

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This argument has been fully considered but is not found to be persuasive. The prior art teaches that a solid dispersion is formed, when mixed with other ingredients, said ingredients not being excluded by the comprising language of the claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera Sheikh whose telephone number is (703) 308-

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4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

